

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

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**IN RE: ETHICON, INC.,  
PELVIC REPAIR SYSTEM PRODUCTS  
LIABILITY LITIGATION**

**MDL No. 2327**

**2:12-md-0327**

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**THIS DOCUMENT RELATES TO:**

**HON. JOSEPH R. GOODWIN**

*Cynthia Newman v. Ethicon, Inc., et al No. 2:14-cv-  
24066*

**RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD**

My name is Konstantin Walmsley. I have been retained by the Tracey & Fox Law Firm to give medical opinions related to Cynthia Newman. I am being compensated at the rate of \$500 dollars/hour. My curriculum vitae is attached. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical and scientific certainty. My reliance list is attached.

With respect to background, training and experience, I graduated college from the University of Pennsylvania with a B.A. in chemistry (Honors) in 1992. Thereafter, I attended Vanderbilt University Medical College graduating in 1997 with a M.D. degree. Additionally, prior to attending medical school, I was employed as a research assistant in the Department of Surgical Metabolism at the Memorial Sloan Kettering Cancer Center in New York, followed by a position as a research assistant in the Department of Neurosurgery at the Graduate Hospital in Philadelphia. Following same, I did a research fellowship in the Department of Physiology (diabetes summer fellowship) in Nashville, Tennessee. From 1995 to 1996, I completed a research scholarship at the Howard Hughes Medical Institute, Laboratory of Tumor Immunology and Biology at the National Cancer Institute, under the auspices of the National Institute of Health in Bethesda, Maryland. From 1996 to 1997, I undertook a position as research assistant in the Department of Urology at Vanderbilt University Medical College, completing same in

1998. Thereafter, I undertook a residency in urology at New York Presbyterian Hospital-Cornell Medical Center which I completed in 2003.

I then became clinical instructor in female urology and voiding dysfunction at New York Presbyterian Hospital-Columbia campus, while simultaneously holding the position of Director of Urodynamics in the Department of Urology at Helen Hayes Hospital. In 2004, I became associate urologist and ultimately a partner at Montclair Urological Group, a position I currently hold although the group has been consolidated into Urology Group of New Jersey and subsequently New Jersey Urology. I have held the positions of both President and Vice President of Medical Staff at Hackensack University Medical Center-Mountainside Hospital, Montclair, New Jersey where I have also held the position of Chairman of the Board of Trustees from 2014 to 2016, and Chairman of the Department of Surgery from 2013 to present. Further, I am Co-Chairman of the Credentialing Committee at said institution. I have recently been named an assistant professor of Urology at Seton Hall University School of Medicine in 2018. I have published numerous articles, abstracts and presentations and have been the recipient of multiple awards and acknowledgements. A full listing of same is included in the attached curriculum vitae which is current as of the date of this report.

I am a licensed physician in the State of New Jersey and a board-certified urologist. I am familiar with the evaluation and treatment of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices. Specifically, I am familiar with Ethicon's products, including but not limited to the TVT sling. I have implanted these devices in my patients. I have attended training provided by mesh manufacturers, including Ethicon, regarding these devices. I have reviewed the IFU's for the Ethicon products and reviewed the independent medical literature. Additionally, I have explanted mesh and performed other revision procedures on SUI and POP kits.

In light of my training, knowledge, experience, and qualifications set forth above and in the attached CV, I am familiar with the standards of care applicable in the jurisdiction where the Plaintiff resides as to surgical technique for implantation of the below-referenced Ethicon devices.

Additionally, because of my training, knowledge, experience, and qualifications as set forth above and in the attached CV, I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants. The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, incomplete emptying, and urinary retention), and nerve entrapment.

In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients' complications based upon a review of her medical records and knowledge of her prior medical history. In forming my opinions, I have reviewed and rely on the TVT general report of Dr. Bruce Rosenzweig. The opinions set forth in the general report of Dr. Rosenzweig are consistent with my clinical experience.

### **Clinical History**

- On 2/14/2005 Ms. Newman seen by Dr. Abel for recurrent dysuria and UTIs. She noted significant urinary incontinence with running and exercising along with some urgency. PMH was remarkable for history of bedwetting until a late age and bladder/kidney surgery of uncertain type. No incisions were noted on exam. Surgical history significant for: bladder/kidney surgery as a child; facial trauma reconstruction; gallbladder removal; breast implants; 4 deliveries and Cesarean delivery. ROS was significant for nocturia. Exam was normal except for significant urethrovesical hypermobility. Dr. Abel's impression was significant for symptoms of cystitis with frequency and urgency and nocturia. Samples of Sanctura were given.

- On 3/24/2005 Ms. Newman was Dr. Abel follow up regarding mixed incontinence. The urge portion of incontinence was noted to be improved on Sanctura. However, the primary component of her incontinence was noted to be SUI. Mid-urethral sling was discussed.

- On 3/29/05 Dr. Abel performed cystoscopy and mid-urethral sling for SUI. Dr. Abel did not identify prolapse and confirmed poor urethral support pre-operatively. Foley was placed and mid-urethra marked. Lidocaine and epinephrine were injected. Midline incision was made over mid-urethra. Dissection was carried out on each side. Once the bladder was confirmed to be empty, the TVT was delivered trans-vaginally up to the suprapubic area with trocars on both sides. Cystoscopy confirmed no bladder injury. Sling was positioned in tension free form using catheter in place and curved Mayo scissors. Hemostasis was assured and the procedure concluded in normal fashion.

- On 4/28/2005 Ms. Newman saw Dr. Abel for followup. She described mild persistent bladder irritation. She reported no incontinence and mild dysuria. Exam found no evidence of infection or erosion. PVR was minimal. UTA samples were given.

- On 3/10/2006 Ms. Newman saw Dr. Abel for recurrent UTI and SUI with mild urinary frequency and urgency. She noted Ms. Newman was not tolerating the side effects of Sanctura. She reported urine loss. Bladder scan was performed. She was switched to Vesicare and Uroblue.

- On 5/13/10 Ms. Newman saw Dr. Abel. She reported uncontrolled urine loss. Nocturia was reported x 3 per night and frequency x4 per night. Bladder scan was performed and PVR was noted to be 0.

- On 6/21/10 Dr. Abel performed cystoscopy and urodynamics. On cystoscopy no mesh was seen in the vagina, urethra, or bladder. No tumors, stones, or other foreign bodies were

noted. 45 degree deflection was noted on Q-tip test. No trabeculations of the bladder wall were noted.

- Voiding diary was remarkable for high bladder volumes and high fluid intake. Leakage was noted with high volume and behavior adjustments were discussed. MRI findings were incorporated and revealed some degree of degenerative disk disease. Urodynamics suggested detrusor overactivity at volume of 350cc. No pelvic floor tenderness was demonstrated on pelvic exam. Palpation of the left and anterior vaginal wall induced urge to void. Vesicare was prescribed. The Urodynamic report notes some atrophic changes.

- On 4/7/11 Ms. Newman saw Melissa Prevatte, NP. She reported left side hip/groin pain for 6-7 months. No vaginal symptoms were reported. Exam found tenderness over left lateral pubis region. She was stated on Celbrex for pelvic joint and thigh pain.

- On 4/8/11 Ms. Newman went to the ER at Stone Crest Medical Center for abdominal pain with onset for week/months. Pain was reported as waxing and waning. She was prescribed Percocet/Phenegan/Ativan.

- On 4/12/11 Pelvic MRI found mild degenerate disc disease and facet arthropathy L5-S1. Mild increased signal bilateral gluteus medius/minimus insertions most likely representing normal variation.

- On 7/21/11 Ms. Newman saw Dr. Dickinson for leakage and left groin pain for 4 months. She reported leakage when she coughs or sneezes. She reported wearing pads all the time. She reported pain after intercourse. Pelvic MRI and CT was noted to be negative. Medication list included: Sanctura, Diflucan; UTA; Estrace; Uroblue; Fluoxetine. Exam found formal urethra and meatus. No tenderness was noted over the sling or in the vagina.

- On 8/28/13 Ms. Newman saw Dr. Jarnigan for (urinary incontinence) UI and pelvic pain. Notes suggest Ms. Newman trialed PT but denied benefit. Dr. Jarnigan's assessment included: AUB; Pelvic Pain; UI; Menorrhagia; History of blood clot secondary to BCPs, and vaginal atrophy.

- In 10/13/13, Ms. Newman complained to Dr. Jarnigan pain on the L side of urethra. Records provide patient with positive pain on left arm of urethra where sling is. Patient also with AUB.

- On 2/24/14, Ms. Newman was Dr. McCullum for painful lymph nodes under the arms and reflux. HPI noted left lower back pain which Ms. Newman believed was related to the TVT. Dr. McCullum's assessment includes abdominal pain, LLQ pain, as persistent issues.

- On 3/6/14 Ms. Newman saw Dr. Tatalovich. Assessment include: UI, Chronic LLQ; LLQ abdominal wall mass; vaginal atrophy; postmenopausal vaginal bleeding; muscles spasm; and myalgia. She reported change in bladder habits and pelvic pain. Exam found mild bladder tenderness and severe vaginal atrophy. Pelvic floor was noted to be tender on L side.

- On 3/19/14 Ms. Newman saw Dr. Tatalovich. Assessments include: Chronic LLQ pain; LLQ abdominal wall mass; post menopausal vaginal bleeding; vaginal atrophy; muscle spasm; and myalgia. She reported a change in bladder habits and pelvic pain. Exam found a L groin mass; mild bladder tenderness and severe vaginal atrophy. Vaginal estrogen was discussed.

- On 3/20/14 pelvic CT found normal appearing bowel. No regional inflammatory stranding or ascites. No lymph node enlargement. Bladder not well distended. No mass in either groin or abdominal wall detected.

- On 6/18/15 Ms. Newman saw Dr. Tatalovich. Assessments include: LLQ pain; UI; post-menopausal vaginal bleeding; LLQ abdominal wall mass; vaginal atrophy; and muscle spasm. She reported her pain level as the same and that she wanted the sling out. Exam found mild tenderness and severe vaginal atrophy. A 3cm palpable mass was located in the left groin. Pelvic floor musculature was noted as tender on the left side.

- On 8/9/15 Ms. Newman saw Dr. Ward for groin pain at Vanderbilt Medical Center. Exam found mild atrophy; stage 2 cystocele, stage 1 uterine prolapse. Assessment included: mixed incontinence; constant leakage while walking; urinary urgency and frequency; nocturia x 2; tender left inguinal mass suspicious for lymph node, firm, mobile, associated dyspareunia, no pain at side of prior retropubic sling, kegel 3/5, no muscle spasm or myalgia, fecal urgency and fecal incontinence of liquid stool since cholecystectomy.

- An 8/26/15 soft tissue ultrasound found normal appearing groin lymph node in region of left groin mass.

- On 10/28/15 Ms. Newman saw Dr. Milam for UDS.

- On 9/14/17 Ms. Newman saw Dr. Jarnigan for incontinence. ROS was significant for painful intercourse and pelvic pain, nocturia, bladder incontinence, frequent urination, and incontinence. Examination found atrophic urethra and vagina, cystocele, and levator tenderness. She was started on Premarin.

- On 9/27/17 Ms. Newman saw Dr. Jarnigan for urodynamics. Assessments included: SUI; UI; midline cystocele; vaginal atrophy; ISD; and IBS. She was started on Symax. She was counseled on retropubic sling, cystoscopy, and injections of pelvic floor muscles.

- On 11/20/17 Ms. Newman saw Dr. Jarnigan for a preoperative visit. Examination noted suprapubic tenderness with palpable nodule of L side of suprapubic area. Vaginal examination found tender L levator and vaginal tissues were noted to be much improved. Assessments include SUI; ISD; enthesopathy of pelvis, myalgia of pelvic floor, suprapubic mass. Treatment was changed to adjustable sling, cystoscopy, excision of left suprapubic nodule, possible paravaginal repair. She was started on Vibramycin, Mobic, Nucynta.

- On 12/27/17 Ms. Newman underwent excision of prior sling and shaving of the pubic bone irritation/inflammation, adjustable sling, cysto. Findings include inflammatory area related to the prior sling being densely adhered to the pubic on the left side. During the vaginal portion of the procedure the sling was removed from sulcus to sulcus. Attention was turned to the suprapubic region. An incision was made above the pubic bone and dissection carried down the anterior abdominal wall. Dissection identified a nodule/knot and the prior sling was dissected off the pubic bone. Roughened area was filed down and irritated tissue was removed. New sling was placed through vaginal incision. New sling was a Reemex system for female incontinence. Ref: SREM-01.

- On 12/29/17 Ms. Newman presented for sling adjustment. PVR was 1050ml. The adjuster was removed and incision closed. Ms. Newman was counseled that due to difficulty voiding the sling could not be tightened at that time.

- On 1/3/18 Ms. Newman saw Dr. Jarnigan for distended abdomen/urinary issues/spasms. Pain was noted to be less than pre-op. PVR was 150ml. Abdominal exam noted bruising consistent with dissection.

- On 2/7/18 Ms. Newman saw Dr. Jarnigan for 6 week post op visit. Pain was noted to have improved and UI was noted to have worsened. Examination found hypermobile urethra. Patient was given a trial of Mybetriq.

- On 3/8/18 pelvic radiograph found small radio-dense foreign body superimposed over low central pelvis.

- On 3/12/18 Ms. Newman underwent adjustment of adjustable sling and trigger point injection of left levator muscles, left obturator muscles and surrounding pubic bone. Procedural indications include stress incontinence. Procedural description notes Kenalog in around the levator muscle on the left side as well as around the pubic bone area where scarring had taken place. No evidence of trauma to bladder was noted. Cystoscopy found scatter mucosal petechial hemorrhages noted on second filling and moderate trabeculation on initial filling.

- On 3/15/18 Ms. Newman followed up with Dr. Jarnigan for open incision and leakage of urine. PVR was 150ml. Abdominal exam revealed some oozing. She was instructed to catheterize due to incomplete emptying.

- On 4/25/18 Ms. Newman saw Dr. Jarnigan for 6 week post op visit. She reported tenderness with the sling adjuster. Current symptoms noted to included spontaneous leakage and retention. Exam found slight over correction of urethra and vaginal atrophy. Patient was counseled on loosening the sling.

- On 4/3/19 Ms. Newman saw Dr. Jarnigan for possible prolapse and complaints related to urge incontinence. Abdominal exam was able to palpate the adjuster suprapubically. Vaginal exam found small cystocele. Bladder was non-tender. Removing the adjuster was discussed.

### **Methodology**

In determining the specific cause of an injury in the medical context it is necessary to “rule in” potential causes of the injury, and then by process of elimination, to “rule out” the least likely causes to arrive at the most likely cause. The process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries. I have used this methodology in arriving at my opinions in this case.

### **Opinion No. 1**

Ms. Newman’s dyspareunia, suprapubic pain and left sided pelvic pain was caused by the TVT. Causes of suprapubic pain/pelvic pain/dyspareunia include: acute urine retention, UTI, cystitis, pelvic inflammatory disease, kidney issues, dysmenorrhea, ovarian cyst, endometriosis; scarring; paraurethral banding; infection; atrophy, and neuromuscular injury. In addition, chronic inflammation, mesh contraction, scar plate formation, and migration secondary to contraction can cause dyspareunia, suprapubic pain and pelvic pain. The 12/27/17 operative report notes inflammation and the sling being densely adhered to the pubic bone consistent with where she reported pain. The operative report also describes a nodule/knot during retropubic dissection and that irritated tissues were removed. The 2/7/18 visit notes provides that her pain had improved following removal of the TVT sling. The 4/3/19 visit note provides no tenderness on abdominal or vaginal exam. The reduction in suprapubic and left side pelvic pain/ dyspareunia following removal of the sling and injection enables me to conclude the TVT was causally related to Ms. Newman’s dyspareunia, suprapubic pain and left side pelvic pain prior to the removal procedure. Further, I have considered other etiologies of dyspareunia, suprapubic pain and left side pelvic pain through a differential diagnosis and have excluded them.

### **Opinion No. 2**

Ms. Newman’s has urinary dysfunction manifested as SUI and urgency urinary incontinence(UUI). The TVT was ineffective in treating the stress incontinence portion of her in

urinary dysfunction. Further, following the placement of the TVT the urge portion of her incontinence was exacerbated despite medication. It is my opinion the placement of the TVT and properties of the TVT exacerbated the urge portion of her incontinence due to mesh contraction and resultant obstruction. Causes and exacerbating factors of UUI include bladder cancer, bladder inflammation, infection, and nerve injury. I have reasonably excluded these etiologies as independent exacerbating factors to Ms. Newman urge incontinence based on differential diagnosis and medical history.

In addition, Ms. Newman currently has UUI and abdominal pain secondary to the adjustable sling implanted on 12/27/17. The implant of the adjustable sling was a foreseeable extension of the failure of the TVT to correct her SUI and the complications secondary to the TVT which required surgical removal of TVT mesh. The adjustable sling placed in Ms. Newman is in part marketed as a “redo” sling indicated in the situation of failed prior mesh sling.

Based on the foregoing analysis, and based on my education, training, experience and knowledge, it is my opinion to a reasonable degree of medical probability the cause of Mrs. Newman’s urinary dysfunction is attributable to the TVT.

Because of the scarring related to the TVT sling and its removal, redo sling operations (such as the adjustable sling used in this circumstance) have a higher failure rate and often are only partially successful and/or fail altogether. Within a reasonable degree of medical certainty, Ms. Newman will likely continue to suffer from voiding dysfunction whether the adjustable sling is adjusted, revised, or abandoned in favor of another anti-incontinence procedure.

### **Case Specific Opinion No. 3**

Ms. Newman was a candidate for alternative procedures and alternative designs. Such alternatives include: native tissue repair using absorbable suture; autologous fascia sling; biologic graft; and/or lightweight mesh slings such as Ultrapro. Such alternatives have high efficacy in treating incontinence and substantially reduce or eliminate the risk of chronic inflammation and chronic foreign body reaction which caused injury to Ms. Newman.

To a reasonable degree of medical certainty, it is my opinion that the TVT sling device caused Ms. Newman’s conditions including continued and worsening voiding dysfunction, vaginal/pelvic pain, and dyspareunia. In addition, it is my opinion to a reasonable degree of medical certainty she will experience continued and ongoing complications and need additional medical treatments in the future related to the permanent complications she suffered from the inadequacies and implantation of the TVT sling. I reserve the right to amend and/or supplement this report if new discovery or facts necessitate amendment or supplementation.